DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

I-011669-D-0008-OT

AUG 0 1 2008

U.S. Fish and Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Request for an amended authorization for marine finfish treated with hydrogen peroxide

Dear Dr. Erdahl:

We grant your request dated April 28, 2008, to amend the authorization for use of 35% PEROX-AID (hydrogen peroxide). 35% PEROX-AID is proposed for the control of mortality due to certain ectoparasites in a variety of freshwater and marine finfish and for the control of mortality due to external columnaris and bacterial gill disease in freshwater-reared finfish.

AMENDED FOOD-USE AUTHORIZATION

Your authorization remains valid for the conditions described in our authorization letter dated December 19, 2007 (I-011669-A-0000-OT). In addition, you are authorized to treat marine finfish reared in sea cages in open-water with an initial treatment concentration of 400 mg/L hydrogen peroxide (35% PEROX-AID) for a treatment duration of 45 minutes for the control of mortality caused by external parasites; you should count fish treated in this manner towards the 21 million fish allotted in our letter dated December 19, 2007.

We have no human food safety concerns with the use of 400 mg/L hydrogen peroxide (35% PEROX-AID) for 45 minutes, administered as immersion therapy to marine finfish species reared in sea cages in open-water aquaculture operations.

INVESTIGATIONAL LABELING

You provided intended investigational labeling language in your A-0000 submission. This labeling is consistent with the requirements set forth in 21 CFR 511.1(a) and (b). The investigational labeling should be affixed to your investigational drug product prior to shipment and this investigational label should be affixed to each individual drug container.

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION

The new animal drug regulations, Section 511.1(b)(3) and (4) require the sponsor to submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals. The agency has devised a form which you as the sponsor may use to report shipments for clinical trials. You may file the notice of the drug shipment electronically to CVM. Please refer to the Center's electronic submission information on the CVM website at http://www.fda.gov/cvm/esubstoc.html.

You must maintain records of dates, amount of drug received in each shipment, and batch or code mark of each shipment for a period of two years after such shipment and delivery. These records should be made available for inspection and copying upon our request.

ENVIRONMENTAL CONSIDERATIONS

We find your claims for investigational uses of 35% PEROX-AID (hydrogen peroxide) in freshwater and marine finfish continue to fall within the categorical exclusion in 21 CFR 25.33(e), subject to the reporting limitations described below. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. These categorical exclusions from the preparation of an EA do not relieve you of the responsibility for determining and meeting all Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of the investigational drug.

You and your site investigators remain responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable groundwater pollution requirements. For all investigational sites covered under this INAD, site investigators must report INAD use of 35% PEROX-AID to the permitting authority authorized to administer the NPDES program for the receiving waters into which a facility discharges [see 40 CFR 451.3(a)]. The permitting authority should also be informed of the acute water quality benchmark of 0.7 mg/L that has been derived by FDA for hydrogen peroxide. The acute benchmark concentration is not an effluent discharge limit and should not be interpreted as such. However, it can be used by the appropriate NPDES authority in conjunction with site-specific information (e.g., allowable size of mixing zone and the extent of dilution in receiving water) to determine if a specific discharge limitation and/or effluent monitoring may be needed for hydrogen peroxide at specific aquaculture facilities.

Please notify CVM if the scope of your investigation changes (e.g., if additional facilities will treat fish, and/or if the protocol changes in ways which could result in increased environmental exposure, etc.).

ADDITIONAL COMMENTS

1. We remind you that the investigational new animal drug must be manufactured, processed, packaged, and labeled in such a way as to maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to investigations made with the drug (21 CFR Parts 210 and 211).

2. In order for us to complete our files, the disposition of all investigational animals and unused drug must be reported to this office, as well as adverse reactions observed. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.

3. You should obtain a material safety data sheet (MSDS) for the investigational drugs and follow the information in the MSDS to protect all individuals who may be exposed to the investigational drug.

4. CVM encourages you to discuss study design issues and submit protocols to the Center for review prior to initiating a study. Guidances for specific study design can be found on the CVM webpage.

5. CVM recommends that you request a meeting to further discuss your proposed claim and product development plan.

6. We encourage you to sample the water during treatment in various locations within the tarp and determine the concentration of the drug at different times during the treatment period such as the beginning, middle, and end of treatment.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Donald Prater, Acting Director, Division of Therapeutic Drugs for Food Animals, at 240-276-8343.

Sincerely,

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine